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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,769	12/14/2005	Konstantin Aleksandrovich Shestibratov	U 015739-4	6030
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			<div>EXAMINER</div> <div>IBRAHIM, MEDINA AHMED</div>	
			<div>ART UNIT</div> <div>1638</div>	<div>PAPER NUMBER</div>
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/531,769

Applicant(s)

SHESTIBRATOV ET AL.

Examiner

Medina A. Ibrahim

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-25 are pending and are examined.

Specification

The disclosure is objected to because of the following informalities: for example, the specification, at page 4, line 8, "20002" is incorrect. Appropriate correction is required.

The specification has not been checked for errors to the extend necessary to determine the presence of all possible errors. Applicant is reminded to check and correct any errors, which the specification may contain.

Claim Objections

At claims 1-25, it is suggested that "characterized in that" be replaced with either --wherein---, to conform with USA format. At claims 2-7, 11-15, and 17-25, "characterized in that" should be replaced with ---wherein---.

At claim 7, ---and--- should be inserted before "Sphaerotheca", for a proper Markush group.

At claim 8, it is suggested that "characterized in that plants for the transformation are selected from the group of dicotyledons" be replaced with ---wherein the plant is a dicotyledon---.

At claim 9, it is suggested "characterized in that for the transformation" be replaced with ----wherein---.

At claim 10, "characterized in that for the transformation" be replaced with ----wherein---.

Claim 5 is an improper dependent claim because it does not refer the claims that it dependent from in the alternative. Appropriate correction is required.

In all claims that recite "genetic material", it is suggested that phrase be replaced with ---a gene---, for clarification.

Claim 7 is objected to in the recitation of "the genetic material codes for resistance". A genetic material confers resistance, but it does not code for resistance. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because step (v) requires a step of preparing subsequent lots of explants in accordance with steps iii) and iv), however, neither step iii) nor step iv) prepares lots of explants. Therefore, clarification is required to more clearly define the metes and bounds of the claim. Claims 2-25 do not obviate the rejection, therefore are included in the rejection.

Claim 1 is indefinite in the recitation of "formation of acquired resistance to abiotic and biotic stresses in the leaf discs" because it is unclear what causes the acquired

resistance. The claim do not recite that the transformation vector contains a gene for acquired resistance. Dependent claims 2-25 are included in the rejection.

Claim 5 is indefinite in the recitation of "a combination of proteins according to claims 2, 3 or 2, 4, or 3, 4 or 2-4" because it is unclear how these proteins are combined. For example, claim 2 recites a protein, while claims 3 and 4 each recites a specific protein, i.e. one that confers reduced frequency of somaclonal variations and another that confers resistance to phytopathogens, respectively. Clarification is required to more clearly define the metes and bounds of the claim.

Claim 16 is confusing in the recitation of "the acquired resistance to abiotic and biotic stresses , growth regulators are excluded from the composition of the cocultivation medium" because it is unclear how the acquired resistance can be excluded from the cocultivation medium since the resistance is not a product. Also, claim 16 is indefinite because "cocultivation medium" lacks antecedent basis in claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing a transgenic garden strawberry and apple plant comprising preparing leaf discs as explants from stock

plants, stagewise inoculation and cocultivation of the explants in media with specified concentrations of specified culture components, does not reasonably provide enablement for a method for producing any transgenic plant comprising method steps that only recite explant preparation without including the specifics of the media that is used during the cultivating with the agrobacterium and regeneration steps. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to a method of producing a transgenic plant by transforming the plant with a vector comprising at least one gene of interest via agrobacterium in a stagewise cocultivation of explants comprising the steps of : selecting one or more leaf segments for use as explants; preparing leaf disks by separating a segment from each disk, wherein the ratio of the section length and explant surface area is from 0.1 mm square, followed by inoculating and co-cultivating the leaf disks with agrobacteria; removing excess agrobacteria from the leaf disks, separating a first lot 10 of explants from the side of the first section; transferring explants onto the selection and regeneration medium; preparing subsequent lots of explants as above until the last lot of explants from the selected leaf disks has been formed; wherein the preparation of each of the subsequent lots of explants is carried out after 1 to 5 days required for the transformation of plant cells and formation of acquired resistance to abiotic and biotic stresses in the leaf disks and for lowering the frequency of somaclonal variations in the transgenic plant; said method wherein the vector

contains genetic material which codes for a protein which contributes to lowering necrosis in the step of transformation or a protein including PR-1, PR-2, PR-3, PR-4, PR-5 which enhances the plant resistance to phytopathogens or combinations thereof, wherein the genetic material confers resistance to specified fungi species; said method wherein plant is an apple, pear, garden strawberry, carrot, and tomatoes, or a specific cultivars of garden strawberry; said method wherein the composition of the selection medium and regeneration medium includes specified concentrations of TDZ, IBA and kanamycin.

Applicant teaches preparation of stock plants from the garden strawberry varieties feyerverk and seletka as source of explants (pages 12-13); preparation of leaf discs as explants; leaf disks were cut with a scalpel on a Petri dish in the presence of a small quantity of liquid MS medium ; from 10--15 mm leaf disk (in a direction 15 of the central vein) a narrow strip having a width not more than 2 mm is cut off and then discarded; the remaining larger part of the leaf disk designated as explants A-5 is used later for the inoculation and co-cultivation of the explants with agrobacterium and for the preparation of subsequent lots of explants A2-A4 (second stage to fourth stage explants); bacterial inoculum of the strains BE21/pBITThau35 and CBE21/pBI121 was prepared (Table 2) for the transformation of the explants. Applicant also teaches stagewise inoculation and co-cultivation of leaf discs explants A5-A1 of the garden strawberry varieties feyerverk and seletka, and the multiplication (M), co-cultivation (CC), elongation root (ER), and regeneration of transformants (RT) media, each with specified components at specified concentrations (Table 1). Applicant further teaches

selection of transgenic tissue, selection of transformants and elimination of agrobacteria after inoculation and co-cultivation with agrobacteria; regeneration of the transformants directly from the cells of the explants and/or via intermediate callus stage (pages 15-16).

Applicant teaches that the expression of thaumatin II expression increased the antifungal resistance of garden strawberry to *Botrytis cinerea* as compared to the control plants; analysis of the influence of stagewise co-cultivation with *Agrobacterium tumefaciens* on the frequency of necrosis in the tissues of explants of garden strawberry showed that the average frequency of the necrosis of the explants transformed according to the instant method is 16.6% as opposed to 54.8% according to the known method; and analysis of the transgenic lines shows that the stagewise co-cultivation with agrobacterium increases the frequency of regeneration of the transgenic shoots of garden strawberry explants and decreased frequency of somaclonal variation as compared to the control plants (Examples 1-10 and 13-16; Table 3-8 and 10-12). Applicant also teaches transformation of apple using similar method steps as the garden strawberry (Examples 11-12; Table 9).

Applicant, however, has not provided guidance regarding the identification of all other plant species that can be transformed with a desired gene including genes that increase resistance to phytophthora pathogens and genes that reduce necrosis, during transformation, using the claimed method. Applicant has provided no evidence to support the applicability of the claimed method to all various species including woody and non-woody plant species. In addition, the claims do not recite necessary steps and media components and concentrations that are required to transform and regenerate

the desired transgenic plants as broadly recited in the claimed method. It is known in the art that each plant species has a unique requirement of culture conditions, chemical components and hormones that are required for efficient regeneration.

The state-of-the-art teaches that specific conditions, chemical components and concentrations are required to achieve a successful transformation of a plant. See, for example, Hansen et al (1999, Trends in Plant Science 4(6):226-231) who teach that successful transformation of plants requires target tissues that are competent for propagation or regeneration, an efficient DNA delivery method, and the ability to recover fertile transgenic plants at a reasonable frequency. Hansen et al also teach that there are variables such as the use of feeder cells, alternative Agrobacterium strains, infiltration of the bacterial and the duration and temperature of co-cultivation need to be tested to ensure success (page 228, 2nd column, 3rd paragraph). Hansen et al (US 6, 162, 965, Applicant's IDS) teach transformation of plants via agrobacterium and methods of reducing agrobacterium induced necrosis in plants. At column 1, lines 14-47, Hansen et al state "(w)hile Agrobacterium transformation works well for plants which are naturally infected and transformed by Agrobacterium in the wild to form tumors and/or hairy roots, it does not work for others.....Even some dicotyledonous plants such as grapes, soybean or pepper..... have nevertheless proved difficult to transform in the laboratory because the preferred target tissues for transformation and regeneration seem to respond poorly to Agrobacterium exposure."

Therefore, in the absence of specific guidance regarding how to select a plant species other than strawberry and apple that are suitable in the claimed method and the

specific culture conditions required for the regeneration of the multitude of plant species required by the claimed method, undue trial and error experimentations would be required for one of ordinary skill in the art to identify potential plant species and then make all possible combinations of media comprising all different kinds of chemical components such as salts, hormones, vitamins, carbon sources and additional additives e.g. explants that have been in stagewise contact with *Agrobacterium*, to identify those, if any that form a transgenic tissue that regenerates to a plant with reduced necrosis and somaclonal variation while exhibiting a desired trait. Therefore, given the breadth of the claims encompassing any plant species; the lack of guidance; unpredictability in the art; and the state of the art as discussed above, the claimed invention cannot be practiced throughout the broad scope without undue experimentation. Therefore, the claims are not enabled. See *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988).

See *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997): where the court held "(P)atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention". See also *in re Fischer*, 166 USPQ 19 24 (CCPA 1970) where the court held the scope of the claims must bear a reasonable correlation with the scope of the enablement.

Remarks

The claims are deemed free of the prior art of record.

Contact information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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MEDINA A. IBRAHIM
PRIMARY EXAMINER

